

In the Abstract:

Please amend the Abstract as follows:

Line 1, delete "system" and insert therefor --computer program product--; and

Line 3, delete "system" and insert therefor --computer program product--.

In the Specification:

Please amend the Specification as follows:

Page 1, line 16, delete "TBA" and insert therefor --09/100,024--;

Page 1, lines 16-17, delete "(Attorney Docket No. 1606.0030001)";

Page 1, line 20, delete "TBA" and insert therefor --09/100,028--;

Page 1, lines 20-21, delete "(Attorney Docket No. 1606.0040001)";

Page 1, line 24, delete "TBA" and insert therefor --09/100,232--;

Page 1, lines 24-25, delete "(Attorney Docket No. 1606.0050001)";

Page 7, line 11, delete "system and method" and insert therefor --method and computer program product--;

Page 7, line 13, delete "system" and insert therefor --computer program product--;

Page 7, line ¹⁶~~17~~, delete "system" and insert therefor --computer program product--;

Page 7, line ¹⁸~~19~~, delete "system" and insert therefor --computer program product--;

Page 7, line 25, delete "system" and insert therefor --computer program product--;

Page 7, line 26, delete "system" and insert therefor --computer program product--;

Page 32, line 17, after "etc." delete "."; and

Page 37, line 18, delete "line resources" and insert therefor --line, resource--.

In the Claims:

Please amend claims 1 and 2 as follows:

1 1. (Amended) A method for [scheduling and] simulating solution preparation[,
2 said solution for use] in a biopharmaceutical production process, comprising the steps of:
3 (1) identifying at least one solution for preparation that is needed in the
4 biopharmaceutical production process [and its associated volume];
5 (2) identifying a [predetermined] calculated start date for preparation of said at least
6 one solution [and at least one successive start date for preparation of said at least one solution]
7 , wherein said calculated start date reflects the time which the preparation of said at least one
8 solution should begin in order to be used in the biopharmaceutical production process;
9 (3) assigning said at least one solution to [a to] a preparation vessel; [and]
10 (4) determining the duration of the [solution] preparation [procedure] of said at least
11 one solution based on the solution preparation parameters of said preparation vessel that said
12 [step of assigning said] at least one solution [to a preparation vessel] was assigned to in step (3);
13 and
14 (5) generating a solution preparation schedule wherein each tasks associated with the
15 preparation of said at least one solution in the biopharmaceutical production process is
16 scheduled;
17 whereby the simulation can be used to determine an optimal design for a
18 biopharmaceutical batch process manufacturing facility.

1 2. (Amended) The method of claim 1, wherein step (1) further comprises the step
2 of calculating the total volume of said at least one solution needed for one process cycle in the
3 biopharmaceutical production process.

Please cancel claim 3 without prejudice or disclaimer.

Please add the following new claims 4-17:

1 --4. A method for simulating the scheduling of solution preparation in a biopharmaceutical
2 production process, comprising the steps of:

3 (1) determining a solution preparation time for each of a plurality of preparation
4 vessels;

5 (2) assigning each of a plurality of solutions that are needed in the
6 biopharmaceutical production process to one of said plurality of preparation vessels;

7 (3) determining a calculated start date and a next preparation date for each of said
8 plurality of solutions;

9 (4) determining an earliest calculated start date and a latest next preparation date
10 for each of said plurality of preparation vessels;

11 (5) calculating a use duration time for each of said plurality of preparation vessels;

12 (6) calculating a cumulative solution preparation time for each of said plurality of
13 preparation vessels;

14 (7) calculating a utilization percentage, using said cumulative solution preparation
15 time and said use duration time, for each of said plurality of preparation vessels;

16 (8) generating, using said calculated start date for each of said plurality of
17 solutions, a shift schedule for each of said plurality of preparation vessels; and

18 (9) generating, using said shift schedule, a time line for the operation of each of
19 said preparation vessel;

20 whereby said time lines contain information that can be used to determine an optimal
21 design for a biopharmaceutical batch process manufacturing facility.

1 5. The method of claim 4, wherein step (1) comprises the steps of:

2 (a) determining a set up time value for each of said plurality of preparation
3 vessels;

4 (b) calculating a water collection rate value for each of said plurality of
5 preparation vessels;

6 (c) determining a mix and weigh time value for each of said plurality of
7 preparation vessels;

8 (d) calculating a solution filtration time value for each of said plurality of
9 preparation vessels;

10 (e) calculating an adjusted filtration time value, by multiplying said solution
11 filtration time value by a pre-determined filtration delay factor, for each of said plurality of
12 preparation vessels;

13 (f) determining a clean-in-place (CIP) time value and steam-in-place (SIP) time
14 value for each of said plurality of preparation vessels; and

15 (g) summing the values from steps (a)-(f) to determine said solution preparation
16 time for each of said plurality of preparation vessels.

1 6. The method of claim 4, wherein step (2) comprises the steps of:

2 (a) determining a total volume value for each of said plurality of solutions; and

3 (b) assigning each of said plurality of solutions to one of said plurality of
4 preparation vessels based on said total volume values for each of said plurality of solutions
5 that are needed in the biopharmaceutical production process.

1 7. The method of claim 4, wherein step (3) comprises the step of:

2 determining said next preparation date for each of said plurality of solutions by adding
3 the number of days per preparation cycle to said calculated start date.

1 8. The method of claim 4, wherein step (6) comprises the step of:

2 (a) determining a preparation cycles per batch value for each of said plurality of
3 solutions; and

4 (b) multiplying said solution preparation time for each of said plurality of
5 preparation vessels by said preparation cycles per batch value for the corresponding one of
6 said plurality of solutions.

1 9. The method of claim 4, wherein step (8) comprises the steps of:

2 (a) generating an initial shift schedule for each of said plurality of preparation
3 vessels; and

4 (b) generating a final shift schedule for each of said plurality of preparation
5 vessels by back scheduling at least one solution associated with said initial shift schedule in
6 order to resolve conflicts between solution preparation cycles for each of said plurality of
7 preparation vessels and shifts of the biopharmaceutical production process.

1 10. A computer program product comprising a computer usable medium having computer
2 readable program code means embodied in said medium for causing an application program
3 to execute on a computer that simulates solution preparation in a biopharmaceutical
4 production process, said computer readable program code means comprising:

5 first computer readable program code means for causing the computer to identify at
6 least one solution for preparation that is needed in the biopharmaceutical production process;

7 second computer readable program code means for causing the computer to identify a
8 calculated start date for preparation of said at least one solution , wherein said calculated start
9 date reflects the time which the preparation of said at least one solution should begin in order
10 to be used in the biopharmaceutical production process;

11 third computer readable program code means for causing the computer to assign said
12 at least one solution to a preparation vessel;

13 fourth computer readable program code means for causing the computer to determine
14 the duration of the preparation of said at least one solution based on the solution preparation

15 parameters of said preparation vessel that said at least one solution was assigned to by said
16 third computer readable program code means; and
17 fifth computer readable program code means for causing the computer to generate a
18 solution preparation schedule wherein each tasks associated with the preparation of said at
19 least one solution in the biopharmaceutical production process is scheduled;
20 whereby the simulation can be used to determine an optimal design for a
21 biopharmaceutical batch process manufacturing facility.

1 11. The computer program product of claim 10, wherein said first computer readable
2 program code means further comprises sixth computer readable program code means for
3 causing the computer to calculate the total volume of said at least one solution needed for one
4 process cycle in the biopharmaceutical production process.

1 12. A computer program product comprising a computer usable medium having computer
2 readable program code means embodied in said medium for causing an application program
3 to execute on a computer that simulates the scheduling of solution preparation in a
4 biopharmaceutical production process, said computer readable program code means
5 comprising:

6 first computer readable program code means for causing the computer to determine a
7 solution preparation time for each of a plurality of preparation vessels;

8 second computer readable program code means for causing the computer to assign
9 each of a plurality of solutions that are needed in the biopharmaceutical production process to
10 one of said plurality of preparation vessels;

11 third computer readable program code means for causing the computer to determine a
12 calculated start date and a next preparation date for each of said plurality of solutions;

13 fourth computer readable program code means for causing the computer to determine
14 an earliest calculated start date and a latest next preparation date for each of said plurality of
15 preparation vessels;

16 fifth computer readable program code means for causing the computer to calculate a
17 use duration time for each of said plurality of preparation vessels;

18 sixth computer readable program code means for causing the computer to calculate a
19 cumulative solution preparation time for each of said plurality of preparation vessels;

20 seventh computer readable program code means for causing the computer to calculate
21 a utilization percentage, using said cumulative solution preparation time and said use duration
22 time, for each of said plurality of preparation vessels;

23 eighth computer readable program code means for causing the computer to generate,
24 using said calculated start date for each of said plurality of solutions, a shift schedule for each
25 of said plurality of preparation vessels; and

26 ninth computer readable program code means for causing the computer to generate,
27 using said shift schedule, a time line for the operation of each of said preparation vessel;

28 whereby said time lines contain information that can be used to determine an optimal
29 design for a biopharmaceutical batch process manufacturing facility.

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1 13. The computer program product of claim 12, wherein said first computer readable
2 program code means, comprises:

3 tenth computer readable program code means for causing the computer to determine a
4 set up time value for each of said plurality of preparation vessels;

5 eleventh computer readable program code means for causing the computer to calculate
6 a water collection rate value for each of said plurality of preparation vessels;

7 twelfth computer readable program code means for causing the computer to determine
8 a mix and weigh time value for each of said plurality of preparation vessels;

9 thirteenth computer readable program code means for causing the computer to
10 calculate a solution filtration time value for each of said plurality of preparation vessels;

11 fourteenth computer readable program code means for causing the computer to
12 calculate an adjusted filtration time value, by multiplying said solution filtration time value
13 by a pre-determined filtration delay factor, for each of said plurality of preparation vessels;

14 fifteenth computer readable program code means for causing the computer to
15 determine a clean-in-place (CIP) time value and steam-in-place (SIP) time value for each of
16 said plurality of preparation vessels; and

17 sixteenth computer readable program code means for causing the computer to sum the
18 values from steps (a)-(f) to determine said solution preparation time for each of said plurality
19 of preparation vessels.

1 14. The computer program product of claim 12, wherein said second computer readable
2 program code means, comprises:
3 tenth computer readable program code means for causing the computer to determine a
4 total volume value for each of said plurality of solutions; and
5 eleventh computer readable program code means for causing the computer to assign
6 each of said plurality of solutions to one of said plurality of preparation vessels based on said
7 total volume values for each of said plurality of solutions that are needed in the
8 biopharmaceutical production process.

1 15. The computer program product of claim 12, wherein said third computer readable
2 program code means, comprises:
3 tenth computer readable program code means for causing the computer to determine
4 said next preparation date for each of said plurality of solutions by adding the number of days
5 per preparation cycle to said calculated start date.

1 16. The computer program product of claim 12, wherein said sixth computer readable
2 program code means, comprises:
3 tenth computer readable program code means for causing the computer to determine a
4 preparation cycles per batch value for each of said plurality of solutions; and
5 eleventh computer readable program code means for causing the computer to multiply
6 said solution preparation time for each of said plurality of preparation vessels by said
7 preparation cycles per batch value for the corresponding one of said plurality of solutions.

1 17. The computer program product of claim 12, wherein said eighth computer readable
2 program code means, comprises: